

**Citation:**

Bopp MJ, Houston DK, Lenchik L, Easter L, Kritchevsky SB, Nicklas BJ. Lean mass loss is associated with low protein intake during dietary-induced weight loss in postmenopausal women. *J Am Diet Assoc.* 2008;108:1216-1220.

**PubMed ID:** [18589032](#)

**Study Design:**

Randomized Controlled Trial

**Class:**

A - [Click here](#) for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To determine whether dietary protein is associated with loss of lean mass in a retrospective analysis of a caloric restriction and exercise weight-loss intervention in postmenopausal women.

**Inclusion Criteria:**

Overweight and obese postmenopausal women aged 50-70 years (further inclusion criteria published in another cited publication).

**Exclusion Criteria:**

No exclusion criteria was reported in this article, however, it was noted that exclusion criteria was published in another cited publication.

**Description of Study Protocol:**

**Recruitment** overweight and obese women aged 50-70 years recruited from Forsyth County, North Carolina.

**Design** Retrospective analysis of data from a previously conducted randomized controlled trial.

**Blinding used (if applicable):** blinding inherent in laboratory procedure of dual energy x-ray absorptiometry.

**Intervention (if applicable)**

- Diet only group - reduced caloric intake by 2,800 kcal/week
- Diet and low intensity aerobic exercise - reduced caloric intake by 2,400 kcal/week and expended 400 kcal/week through exercise

- Diet and high intensity aerobic exercise - reduced caloric intake by 2,400 kcal/week and expended 400 kcal/week through exercise

### **Statistical Analysis**

- Descriptive statistics were calculated and values reported as mean±standard deviation or frequencies
- One way analysis of variance was used to calculate the differences between the intervention groups
- An alpha level of .05 was used as the nominal type I error rate
- Linear regression analysis was performed to examine the association between lean mass and appendicular lean mass and dietary protein.
- Regression models were adjusted for intervention group, body size (height and baseline lean mass or appendicular lean mass), and change in fat mass.

### **Data Collection Summary:**

#### **Timing of Measurements**

Baseline and 20 weeks.

#### **Dependent Variables**

- Total lean body mass measured using dual energy x-ray absorptiometry
- Appendicular lean body mass measured using dual energy X-ray absorptiometry

#### **Independent Variables**

- Weight loss diet to approximate a 2,800 kcal/week energy deficit using caloric restriction (340-400 kcal/day) and designed to include approximately 25%-30% of energy from fat, 15%-20% of energy from protein, and 50%-60% of energy from carbohydrate (resulting absolute protein intake in this overweight/obese group was 0.47-0.08 g/kg body weight per day.) All participants were provided lunch, dinner and snacks daily from the Wake Forest University General Clinical Research Center metabolic kitchen. Meals were prepared based on each participant's choices from a menu designed by a registered dietitian.
- Exercise energy expenditure of about 400 kcal/week for those assigned to the exercise groups. Exercise was 3 days per week under the supervision of an exercise physiologist.

#### **Control Variables**

- Regression models adjusted for intervention group, body size, and change in fat mass

### **Description of Actual Data Sample:**

**Initial N:** 70 females

**Attrition (final N):** 70 females

**Age:** 50- 70 years, mean age 58 years

**Ethnicity:** 33% African American

**Other relevant demographics:** none reported

**Anthropometrics** (baseline) BMI mean =  $33.0 \pm 3.6$ , Total Lean Mass (kg) =  $52.7 \pm 5.6$ , Body Fat % =  $42.1 \pm 3.3$ ,  $\text{V}_{\text{O}_2\text{max}}$  = 20.67mg/kg/min

**Location:** Forsyth County, North Carolina

## Summary of Results:

### Key Findings:

- Average weight loss was  $10.8 \pm 4.0$  kg ( $-12.2\% \pm 4.2\%$ ) and was not significantly different between groups
- The amount of lean mass lost increased as the amount of total weight lost increased ( $r=0.69$ ,  $P<0.0001$ )
- Participants (from all groups combined) who consumed higher amounts of dietary protein lost less lean mass and appendicular lean mass ( $r=0.3$ ,  $P=0.01$ , respectively)
- There was a significant correlation between protein intake (gm/kg body wt/day) and absolute (kg) fat mass loss ( $r=0.37$ ,  $P=0.001$ )
- In unadjusted regression models, participants who consumed higher amounts of dietary protein lost less lean mass and appendicular lean mass [ $\beta$  standard error: 0.62 (0.24),  $P=0.01$ , and  $\beta$  standard error: 0.46 (0.12)  $P=0.001$ , respectively]. the relationship remained significant after adjusting for intervention group and body size for lean mass and appendicular lean mass, respectively.
- Protein intake remained a significant predictor of lean mass and appendicular lean mass loss even after adjusting for change in fat mass.

### Author Conclusion:

Participants who consumed higher amounts of dietary protein lost less lean mass and appendicular lean mass. Inadequate protein intake during caloric restriction may be associated with adverse body composition changes in postmenopausal women.

### Reviewer Comments:

- *Groups did not differ in body composition, protein intake or weight loss*
- *The study's results were based on protein intakes ranging from 0.47-0.80 g/kg body wt/day with the mean 0.62 g/kg/d. The author acknowledged that one could not infer that this relationship exists at higher protein intakes (above the RDA).*

## Research Design and Implementation Criteria Checklist: Primary Research

### Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)

Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

## Validity Questions

1.	<b>Was the research question clearly stated?</b>	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	<b>Was the selection of study subjects/patients free from bias?</b>	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	???
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	<b>Were study groups comparable?</b>	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	No
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	<b>Yes</b>
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	<b>Yes</b>
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	<b>Yes</b>
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>Yes</b>
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	<b>Yes</b>
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	<b>Yes</b>
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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